K042610

MAY 16 2005

510(k) Summary

Name of Device

Trade Name:	Alergol Pollen Blocker Cream
Common Name:	Pollen Blocker
Classification Name:	Unclassified

Predicate Devices

510(K)	MANUFACTURER	DEVICE	APPROVAL DATE
K981841	RespirAid	BREATHE EASY	10-13-98
K032948	Medpak	Elastic Skin Liquid Bandage	06-25-04

Device Description

Alergol Pollen Blocker Cream is a viscous topical nasal cream consisting of highly refined aliphatic long-chain hydrocarbons for prophylaxis and therapy of allergic rhinitis caused by airborne allergens. The product is applied by finger or cotton swab to the inside surface of the nasal vestibule in the region of the nose flap where it acts as a mechanical barrier to reduce the adverse effects of inhaled allergens. Proper application of the cream makes it more difficult for inhaled allergens to come into contact with the skin in the nasal interior, and thus reduces the intensity of allergic rhinitis symptoms.

The hydrocarbon gel is chemically inert to the body and nasal membranes, and contains no additives. On average, protection lasts for 3 to 5 hours before the cream has to be reapplied. The Alergol Pollen Blocker cream is intended for topical use and provided non-sterile.

Intended Use

The Alergol Pollen Blocker Cream is intended to promote alleviation of mild allergic symptoms (i.e., mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various allergens including environmental pollens, house dust, animal hairs, and dust mites.

Pharmaceutical and Physical and Characteristics

The Alergol Pollen Blocker (5 g nasal ointment) contains only a special pharmaceutical Vaseline (100%), no preservatives, no odoriferous substances, and no other substances. The physical characteristics of the Dr. Theiss Alergol Pollen Blocker Cream is similar to the Kos Polyglycol Cream, a packing material for use in ear surgical procedures. Both creams maintain their consistency for 4-6 hours. The product is also similar to commercially-available pharmaceutical vaseline products.

Safety Testing

By using longer carbon chains, a greater product viscosity is achieved which is an important factor regarding product safety. There have been no reports of any adverse effects during the past 40 years with the use of such products for topical purposes, even in the nasal cavity.

Laboratory and Testing

Appropriate toxicology and pharmacology testing demonstrates that the Alergol Pollen Blocker is safe for topical use as described in the product labelling. The biocompatibility of the Alergol Pollen Blocker cream is consistent with the results of the toxicology and safety performance testing. The Alergol Pollen Blocker does not contain any materials which are subject to the risk of transmission of bovine spongiform encephalitis (BSE). Stability and packaging materials testing demonstrate that the product has a shelf-life of over 5 years at room temperature. The pollen blocker cream is intended for topical use and provided non-sterile.

Summary of Clinical Results

The safety and effectiveness of the Alergol Pollen Blocker Cream has been demonstrated in several clinical studies including two multicenter, prospective, randomized, double-blind, placebo-controlled crossover studies (N=50; N=91) of the anti-allergic effectiveness of the Alergol Pollen Blocker nasal cream in treating patients suffering from allergic rhinitis.

Both studies demonstrate the safety and effectiveness of the product. Symptom scores decreased significantly for patients treated with the Alergol Pollen Blocker Cream by up to 40% ($p = 0.001$) and nasal airflow resistance went down by approximately 50%. Treated patients reported that the blocker cream was well-tolerated and no side-effects occurred as a result of application of the nasal cream.

The methylcellulose control also provided treatment and is not, therefore, strictly a placebo. However, the treatment effect for patients treated with the Alergol Pollen Blocker Cream was more significant than for those treated with the control therapy.

Results from Clinical Trials

In a clinical investigation (S. Schwetz et al. Arch Otolaryngol Head Neck Surgery. 2004;130:979-984) Dr. Theiss Alergol Pollen Blocker Cream was found to be effective for the prophylaxis of symptoms in patients with seasonal or perennial allergic rhinitis.

In this double-blind, randomized, placebo-controlled, crossover study, ninety-one patients were randomly assigned to receive pollen blocker cream (n=43) or carboxymethylcellulose gel (placebo) (n=48).

The efficacy of treatment was assessed by means of nasal provocation testing. The investigators assessed the nasal symptom severity scores (range 0-6) and the changes in nasal airflow after allergen challenge.

Results:

Dr. Theiss Alergol Pollen Blocker Cream was significantly more effective than placebo and reduced the typical symptoms of allergic rhinitis in response to nasal challenge with allergen by nearly 60% (placebo reduced symptoms by 25% *)

The increase in airflow in response to treatment was approximately 20% in the Blocker Cream group compared to 10% in the placebo group.

Patient results can be categorized as follows:

Patient Group	Number of Patients	Percent of Patients	Symptom Score
High Responders	46	51%	Decrease >2
Responders	22	24%	Decrease = 1 or 2
Non-Responders	23	25%	Decrease <1

Approximately 50% of patients were therefore high responders, 25% were responders, and 25% were non-responders.

Dr. Theiss Alergol Pollen Blocker Cream did not produce any adverse effects.

Due to the physical mode of action of the preparation and its topical administration, there are no known interactions with other medicines. Dr. Theiss Alergol Pollen Blocker Cream can therefore be safely combined with other forms of allergy treatment.

Conclusions

By virtue of its physical characteristics and intended use, the Alergol Pollen Blocker Cream is substantially equivalent to devices legally marketed in the United States. Several clinical studies have demonstrated the safety and anti-allergic effectiveness of the Alergol Pollen Blocker nasal cream in treating patients suffering from allergic rhinitis. Methylcellulose vaseline also provides treatment, however the treatment effect for patients treated with the Alergol Pollen Blocker Cream was more significant than for those treated with methylcellulose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2005

Dr. Theiss Naturwaren GmbH
c/o Stuart Portnoy, MD
Senior Director, Medical Device Consulting
PharmaNet, Inc.
815 Connecticut Avenue NW, Suite 800
Washington, DC 20006

Re: K042610
Trade/Device Name: Dr. Theiss Alergol Pollen Blocker Cream
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical recirculating air cleaner
Regulatory Class: Class II
Product Code: NUP
Dated: April 15, 2005
Received: April 18, 2005

Dear Dr. Portnoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K042610

Indications for Use Statement

Device Name: **Alergol Pollen Blocker Cream**

510(k) Number:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION

Prescription Use ____ OR Over-The-Counter Use __X__

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K042610